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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/626,617	07/27/00	DUMOUTIER	L LUD 5664 US

HM12/0716

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EXAMINER

DECLoux, A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/16/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/626,617

Applicant(s)

Dumoutier et al.

Examiner

DeCloux, Amy

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 10, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### SUPPLEMENTAL OFFICE ACTION

1. Applicant's election of Group I, claims 1-12 in Paper No. 7, faxed 5-10-2001, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The species requirement has been withdrawn after further consideration.

2. Claims 13-21 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for stimulating expression of a STAT3 and STAT1 comprising contacting a cell capable of said expression with an amount of human IL-TIF/IL-21, and a method for stimulating expression of a STAT3 and STAT5 comprising contacting a cell capable of said expression with an amount of murine IL-TIF/IL-21, does not reasonably provide enablement for the broader recitation of a method for stimulating expression of any STAT transcription factor comprising contacting a cell capable of said expression with an amount of any IL-TIF/IL-21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed in claims 1-7 without an undue amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the different STAT transcription factors that are expressed upon contacting cells with IL-TIF/IL-21. The instant specification discloses in Example 27 that human IL-TIF/IL-21 stimulates STAT3 and STAT1 but not STAT 5, which is confirmed by a post filing date paper authored by 2 of the instant inventors Dumouotier et al (PNAS 97(18):10144-10149), see entire article, especially page 10146, column 2. The instant specification discloses in Example 21 that murine IL-TIF/IL-21 stimulates STAT3 and STAT 5 but not STAT 1. However, this appears to be contradicted by a post filing date paper authored by 2 of the instant inventors Dumouotier et al (PNAS 97(18):10144-10149), see entire article, especially page 10144, column 1, where it states that murine IL-TIF/IL-21 failed to activate STAT 3 in mice. Applicant is requested to clarify.

In view of the quantity of experimentation necessary, the limited working

examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

5. Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing production of acute phase proteins human serum amyloid A1, alpha chymotrypsin and haptoglobin in a liver cell by human or murine IL-TIF/IL-21, does not reasonably provide enablement for the broader recitation of a method for inducing production of any acute phase proteins in any cell type by any IL-TIF/IL-21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed in claims 8-12 without an undue amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the different STAT transcription factors that are expressed upon contacting cells with IL-TIF/IL-21 from different sources. As discussed above, murine and human IL-TIF/IL-21 activated different STAT transcription factors, and therefore it is not clear what transcription factors will be activated by IL-TIF/IL-21 from different species other than mouse and human. Because transcription factors each regulate the transcription of distinct sets of genes, it is not clear which if any acute phase proteins would be activated by a transcription factors expressed as a result of activation by IL-TIF/IL-21 from different species other than mouse and human. Also because transcription factors each regulate the transcription of distinct sets of genes, it is not clear which acute phase proteins other than human serum amyloid A1, alpha chymotrypsin and haptoglobin would be induced as a result of activation by murine and/or human IL-TIF/IL-21. Also because transcription factors each regulate the transcription of distinct sets of genes, it is not clear which, if any acute phase proteins in cell types other than liver would be induced as a result of activation by murine and/or human IL-TIF/IL-21.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

6.. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to

Serial Number 09/626,617  
Art Unit 1644

4

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Group 1640, Technology Center 1600  
July 12, 2001

*David A. Saunders*

DAVID SAUNDERS  
PRIMARY EXAMINER

ART UNIT ~~182~~ 1644